

REMARKS

Rejection Under 35 USC 112

Claims 19-20 and 33-50 have been rejected under 35 USC 112, second paragraph, as indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. Claims 19, 33, 34, 35, 37, 38, and 46-50 are considered indefinite because the recitation of "adapted for" makes unclear how the device of said claims is modified for achieving the desired function. Claims 20, 36, 39, and 41 are considered indefinite because the recitation of "adapted to" makes unclear how the device of said claims is modified for achieving the desired function. In addition, Claims 19, 20, 34, and 36 are considered vague because, "The claims are not clear in reciting that the testing element is insertable because there is nothing recited in the claims for the testing element to be inserted into." Claims 40, 43-45 are also considered vague because they do not recite limitations which further limit the test device of Claim 38. In response, Applicant has amended Claims 19, 33, 35, 37-39, 41, 46, 48, and 50 to remove the indefinite language "adapted for" and "adapted to." In addition, claims 19, 33 and 50 have been amended so that the claimed testing device is recited as comprising a housing, having a sample application matrix, at least one aperture in the housing to receive a testing element and at least one insertable testing element. Accordingly, each of these claims now clearly sets out the components of the claimed testing device including the housing for the testing element to be inserted into. Claims 20, 34, 36, 40, 43-45, 47, and 49 have been cancelled, thereby obviating the rejection of those claims. Applicant respectfully submits that the rejected claims as amended comply with the requirements of 35 USC 112, second paragraph.

Rejection Under 35 USC 102

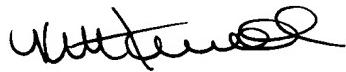
Claims 19, 20, 33, 34, 35, 36, 37 and 50 have been rejected under 35 USC 102(b) as anticipated by Huang *et al.* (US Patent 5,712,172) or May *et al.* (US Patent 5,622,871). In connection with these prior art rejections, the Patent Office has indicated that the rejected claims "are being read as a testing device comprising a sample application matrix and a testing element where the sample application matrix and testing element are related in that they be in liquid-conductive communication". The amendments proposed in claims 19, 33 and 50 as

discussed above, clearly distinguish the presently claimed invention from the cited prior art documents, specifically by making it quite clear that the relationship between the sample application matrix and the "insertable" testing element is that these are separate components which do not come into direct liquid-conductive communication until the testing element is inserted into an aperture in the housing containing the sample application matrix, whereupon the testing element is retained within the housing in liquid-conductive communication with the sample application matrix. Accordingly, the test device of the present invention operates as a collection device for a sample or a plurality of samples in which the sample(s) remain in the collection device until the insertable testing element is inserted into the aperture in the housing to initiate development of the test to identify an analyte of interest in the sample(s). In this regard, Applicant also points out that the testing device of the present invention is particularly suitable for receiving a plurality of samples having discrete origin and aggregating the samples so that a single test may be performed to simultaneously determine the presence of the analyte of interest in the aggregated samples. The devices of the cited prior art documents are not suitable for such aggregation of a plurality of samples since the devices described in these cited references comprise a sample matrix in contact with a test strip so that the addition of a first sample will cause the test to run before any additional sample(s) can be added. Accordingly, the cited references do not disclose or teach a testing device having the features now recited in the amended claims. Applicant thus respectfully submits that the rejected claims are free of the cited art.

Summary

In light of the above amendment, consideration of the subject patent application is respectfully requested. Any deficiency or overpayment should be charged or credited to Deposit Account No. 500282.

Respectfully submitted,



Kevin M. Farrell
Attorney for Applicants
Registration No. 35,505
(603) 433-6300

Portsmouth, NH

Date: 6/24/04

P0057030.DOC